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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,448	11/12/2003	Robert Cherney	PH 7269 DIV 1	8687

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EXAMINER
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SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/706,448	<b>Applicant(s)</b> CHERNEY, ROBERT	
	<b>Examiner</b> Taofiq A. Solola	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: ____.  |

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Claims 1-25, are pending in this application.

Claims 13-25 are drawn to non-elected invention.

### ***RESTRICTION REQUIREMENT***

In response to the restriction requirement mailed 3/10/05, applicant elects example 35, wherein in formula (I), ring B is cyclohexyl; Z is  $-C(O)-$ ;  $R1^a$  and  $R1^b$  together form  $=O$ ; R1 is phenyl; R2 is phenyl; R4 not applicable; R5 is H; R6 is Cl; R7 is  $CF_3$ ; R8, R9, R10,  $R10^a$ , R11 and R12 are each H; R13 is not applicable; n is 1; m and s are each 0; p, q, r and t are not applicable. The election is made with traverse on the basis that it is improper for reasons set forth in MPEP 803.02. However, applicant fails to reference specific passages and paragraph(s) and how they apply in the instant case. Therefore, the restriction is still deemed proper and made FINAL.

Claims 1-12 are being examined in part subject to the election made above by applicant.

### ***Status of Claims***

The Office has reviewed the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention encompasses all compounds within the scope of the claims, which fall into the same class and subclass as the elected compound, but may include additional compounds, which fall in related subclasses. Examination of the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification results in the following:

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In formula (I), ring B is 6-8 cyclohexyl; R1<sup>a</sup> and R1<sup>b</sup> together form =O; Z, R1, R2, R6, R7, R8 and R9 are each as defined in claim 1; R5, R10, R10<sup>a</sup>, R11 and R12 are each H; R4 and R13 are not applicable; n is 1; s is 0; m, p, q, r and t are not applicable. As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 1-12 are withdrawn from further consideration by the Examiner, under 37 CFR § 1.142(b), as being drawn to a non-elected subject matter. The withdrawn compounds are patentably distinct from the elected invention as they differ in structure and element and would require a separate search. In addition, a reference, which anticipates the elected invention, would not render obvious the non-elected subject matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutrufo et al., Eu. J. Pharm. (1999), Vol. 374, No. 2, pages 277-283.

Cutrufo et al., disclose the compound per attached abstract.

### ***Double Patenting Rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,706,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because even after amending the instant claims within the allowable scope set forth above under Status of Claims, most of the allowable compounds are in the patented claims of US 6,706,712.

### ***Objection***

Claims 1-12, are objected to for containing non-elected subject matter, and would be allowed if the claims were amended within the scope of the elected invention as suggested above.

### ***Rejoinder of Claims***

Claims 13-26 would not be rejoined because the claimed utilities are deemed speculations since there are no biological assays or journal articles to support them. Modulation without beneficial effect of treating a disease is not a utility. Therefore, the utilities must be limited to those having biological assays or journal articles in the specification.

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***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**

Group 1626

April 21, 2005